

**What is claimed is:**

1. An excisional biopsy device, comprising:

a tubular member having a window near a distal tip thereof;

5 a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and

a tissue collection device externally attached at least to the tubular member, the tissue collection device collecting tissue severed by the cutting tool as the biopsy device is rotated and the cutting tool is bowed.

10 2. The excisional biopsy device of claim 1, wherein the distal portion of the cutting tool comprises a thin ribbon sharpened on a leading edge thereof.

3. The excisional biopsy device of claim 2, wherein the leading edge of the thin ribbon is serrated.

15 4. The excisional biopsy device of claim 1, wherein the tubular member comprises an internal guide allowing a proximal portion of the cutting tool to slide therein when a proximal end of the cutting tool is pushed in a distal direction or pulled in a proximal direction.

5. The excisional biopsy device of claim 1, wherein the cutting tool further comprises:

20 an interior lumen; and

a plurality of through holes in the distal portion thereof, the through holes being in fluid communication with the interior lumen.

6. The excisional biopsy device of claim 1, wherein the tissue collection device comprises a bag within which the severed tissue is collected.

7. The excisional biopsy device of claim 6, wherein an opening of the bag is at least co-extensive with the window in the tubular member.

5 8. The excisional biopsy device of claim 1, wherein the tissue collection device is configured to open and to close as the cutting tool is selectively bowed and retracted, respectively.

9. The excisional biopsy device of claim 8, wherein the tissue collection device comprises a bag attached to the tubular member and to a trailing edge of the distal portion of  
10 the cutting tool, the bag opening and closing as the cutting tool is bowed and retracted, respectively.

10. The excisional biopsy device of claim 1, further comprising an ultrasound sensor mounted within the distal portion of the tubular member, the ultrasound sensor being disposed within the tubular member so as to image tissue about to be cut by the cutting tool  
15 as the biopsy device is rotated.

11. The excisional biopsy device of claim 10, wherein the ultrasound sensor is electrically connected to at least one data processing and display device to allow one of a real time and near real time graphical representation of the tissue to be cut.

12. The excisional biopsy device of claim 1, wherein the distal portion of the  
20 cutting tool is electrically connected to an RF power source.

13. The excisional biopsy device of claim 12, wherein the distal portion of the cutting tool comprises a thin wire.

14. An invasive interventional device for soft biological tissue, comprising:

a rotatable tubular member having a distal tip adapted to penetrate the tissue;

a work element disposed near the distal tip of the tubular member, the work element acting upon the tissue coming into contact therewith as the tubular member rotates;

an ultrasound transducer disposed near the distal tip of the tubular member and away  
5 from the work element, so that the transducer sweeps a plane within the tissue ahead of the work element as the tubular member rotates; and

means for controlling an operation of the work element based upon information gathered from the ultrasound transducer.

15 15. The device of claim 14, wherein the ultrasound transducer is tuned within a range from about 7.5 MHz to about 20 MHz.

16. The device of claim 14, wherein the ultrasound transducer is disposed within the tubular member at an angle  $\alpha$  relative to the work element, the angle  $\alpha$  being no smaller than that necessary to effectively control the operation of the work element in response to the information gathered from the transducer as the tubular member rotates.

15 17. The device of claim 16, wherein the angle  $\alpha$  is less than about 180 degrees.

18. The device of claim 14, wherein the work element comprises at least one device selected from the group consisting of: an abrasive device, a reciprocating cutting device, a bowing cutting device, an electrosurgical device, a laser device and a vibrating device.

20 19. The device of claim 14, wherein the ultrasonic transducer is connected to at least one data processing and display device to allow an operator of the device to ascertain a structure of the tissue and to control the operation of the work element before the tissue comes into contact with the work element as the device rotates.

20. The device of claim 14, wherein the work element comprises a cutting tool, a distal end of the cutting tool being attached near the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of a window in the tubular member and to retract within the window.

5 21. The device of claim 20, wherein the controlling means include means for selectively bowing and retracting the cutting tool.

22. The device of claim 21, wherein the controlling means includes one of a manually operable push knob and a manually operable turn knob

23. An excisional biopsy method for soft tissue, comprising the steps of:

10 inserting a generally tubular member into the tissue, the tubular member including a cutting tool adapted to selectively bow away from the tubular member and an external tissue collection device near a distal tip of the tubular member;

rotating the tubular member;

selectively varying a degree of bowing of the cutting tool;

15 collecting tissue severed by the cutting tool in the tissue collection device; and

retracting the tubular member from the soft tissue.

24. The method of claim 23, wherein the rotating step is carried out by manually rotating the tubular member.

25. The method of claim 23, wherein the tubular member further includes an

20 imaging transducer and wherein the method further comprises the steps of:

displaying information received from the transducer on a display device; and

varying the degree of bowing of the cutting tool based upon the displayed information from the imaging transducer.

26. The method of claim 25, wherein the cutting tool comprises an electrosurgical blade and wherein the method further comprises the step of varying a power applied to the electrosurgical blade based upon information received from the transducer.

27. The method of claim 23, further comprising the step of stabilizing the soft tissue in an uncompressed state prior to the inserting step.

28. The method of claim 23, further comprising the step of controlling the cutting tool to assume a non-extended state prior to the inserting step and before the retraction step.

29. The method of claim 28, wherein the tissue collection device assumes a closed configuration when the cutting tool assumes the non-extended state.

30. The method of claim 23, wherein the extension of the cutting tool is controlled by selectively and manually pushing and retracting a proximal end of the cutting tool in the distal and proximal directions, respectively.

31. The method of claim 23, wherein the cutting tool comprises an interior lumen and a plurality of through holes in fluid communication therewith, and wherein the method further comprises the step of delivering at least one fluid to the tissue via the plurality of through holes.

32. An imaging and treatment method for soft tissue, comprising the steps of:  
inserting a tubular member into the soft tissue, the tubular member including an ultrasonic transducer mounted near a distal end of the tubular member;  
rotating the tubular member within the soft tissue;

displaying an output of the ultrasonic transducer on a display device; and  
acting upon the soft tissue based upon the displayed output.

33. The method of claim 32, wherein the ultrasonic transducer is tuned to within a frequency range of between about 7.5 MHz to about 20 MHz.

5 34. The method of claim 32, wherein the acting step includes a step of excising a selectively variable volume of soft tissue from a main tissue mass.

35. The method of claim 34, further including a step of collecting the excised volume of tissue in a tissue collection device mounted externally to the tubular member.

36. An excisional biopsy device, comprising:  
10 a tubular member having a first and a second window near a distal tip thereof;  
a cutting tool configured to selectively bow out of the first window and to retract within the first window; and  
a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is  
15 fitted within the tubular member.

37. The device of claim 36, wherein the removable core is adapted to snap fit within the tubular member.

38. The device of claim 36, wherein the active transducer element includes an ultrasound transducer.

20 39. The device of claim 36, wherein the removable transducer core comprises a tapered distal tip configured to readily penetrate soft tissue.

40. The device of claim 36, further comprising an external tissue collection device attached at least to the cutting tool.

41. The device of claim 40, wherein the tubular member further comprises a recessed section adjacent a trailing edge of the cutting tool, the recessed section being adapted to receive the external tissue collection device.

42. The device of claim 36, further comprising an expandable sheath, the expandable sheath being adapted to receive the removable transducer core and the tubular member.

43. Method of excising a lesion from soft biological tissue using an excisional biopsy system including a generally tubular member having a cutting tool, a removable transducer core adapted to fit within the tubular member and an expandable sheath, comprising the steps of:

fitting the transducer core through the expandable sheath,

inserting the transducer and sheath through an incision in the tissue;

15 imaging a target site within the tissue by energizing the transducer core,

removing the transducer core from sheath while leaving the sheath in place within the tissue;

securing the core within the generally tubular member so the core faces outwardly from the tubular member;

20 sliding the tubular member through the expandable sheath until the cutting tool is positioned adjacent the lesion;

cutting the lesion with the cutting tool; and

retracting at least the tubular member from the incision.

44. The method of claim 43, further comprising the step of stabilizing the breast in one of an uncompressed and a slightly expanded state prior to the inserting step.

45. The method of claim 43, wherein the sheath remains within the tissue after the  
5 retracting step and wherein the method further comprises the step of:

re-inserting the transducer core within the sheath and imaging the target site to insure that the lesion has been excised.

46. The method of claim 43, further comprising the step of collecting the cut lesion within an external tissue collection device secured to the tubular member.

10 47. The method of claim 43, wherein both the tubular member and the sheath are retracted from the incision.

48. An excisional biopsy device, comprising:

a single use disposable tubular member having a window near a distal tip thereof, the tubular member including a cutting tool, a distal end of the cutting tool being attached near  
15 the distal tip of the tubular member, at least a distal portion of the cutting tool being configured to selectively bow out of the window and to retract within the window; and

a single use disposable tissue collection device externally attached at least to the tubular member, the tissue collection device collecting tissue severed by the cutting tool as the biopsy device is rotated and the cutting tool is bowed.

20 49. An excisional biopsy device, comprising:



a single use disposable tubular member having a first and a second window near a distal tip thereof, the tubular member including a cutting tool configured to selectively bow out of the first window and to retract within the first window; and

- 5 a removable transducer core, the transducer core including an active transducer element configured to face out of the second window when the removable transducer core is fitted within the tubular member.